CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Comments on Proposed Regulations to Implement Section 305 (Registration) of the Bioterrorism Act, Docket No. 02N-0276

The Food and Drug Administration (FDA) has published proposed regulations implementing section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), which requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the FDA no later than December 12, 2003.

On behalf of the Center for Science in the Public Interest (CSPI), we are writing to comment on the proposed registration requirements necessary to protect the U.S. food supply from intentional contamination and adulteration. CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by 800,000 subscribers to its *Nutrition Action Healthletter*.

FDA's prompt implementation of the Bioterrorism Act is a necessary step in assuring there is swift and appropriate response in the event of a terrorist attack on the American food supply. Recent news reports that terrorists have developed materials to manufacture *Salmonella* and botulinum and may have intended to poison the food supply of American military troops in

Afghanistan demonstrate that there is a real and serious threat to the food supply.[1]

While the Bioterrorism Act provides FDA with additional tools to respond quickly in the event of a threat to the American food supply, we support the following measures as a way to strengthen the registration provisions of the Act:

- further clarification of the activities that FDA considers de minimis as opposed to significant for purposes of determining which foreign facilities must register;
- requiring specific product-category information as part of the registration requirement;
- requiring mandatory notification when a facility goes out of business; and
- clarification of the provisions warranting revocation or suspension of registration.

At the same time, we do not believe FDA has authority to create additional exemptions from the registration requirement, particularly on the basis that facilities may have registered with other federal agencies for other purposes.

The registration provisions of the Bioterrorism Act provide the FDA with an important tool in the effort to prevent or minimize a terrorist attack on the American food supply. The more information FDA has concerning facilities and the foods they manufacture, process, pack or hold, the better able the agency will be to detect intentional efforts to potentially contaminate those foods and protect American consumers. However, FDA's efforts should not stop there. The agency must also work to increase the number of import and domestic inspections and improve disease outbreak surveillance and investigation to provide rapid information on foodborne disease outbreaks.

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[1] Barton Gelman, *Al Queda Near Biological, Chemical Arms Production*, THE WASHINGTON POST, Mar. 24, 2003, at A01. See also James Risen and Don Van Natta, Jr., *Plot to Poison Food of British Troops is Suspected,* THE NEW YORK TIMES, Jan. 24, 2003, at A1.

1. *The Rule Should Clarify The Nature of De Minimis Exemptions for Foreign Facilities*

Section 1.226(a) of the proposed rule identifies certain facilities that are exempt from the registration requirement. Among others, foreign facilities are not required to register if the food from those facilities undergoes "further manufacturing/processing (including packaging) by another foreign facility outside the United States." However, the facility must register if the further manufacturing or processing at the subsequent facility consists of adding labeling or "any similar activity of a de minimis nature."

In the preamble to the proposed rule, FDA has identified one type of activity in addition to labeling that it views as de minimis – adding plastic rings to the outside of beverage bottles to hold them together.[2] FDA also explains that requiring registration of foreign facilities that conduct "a significant activity" with respect to the food, among other things, ensures that FDA has contact information for foreign facilities whose operations would be expected to affect food exported for consumption in the United States.[3]

To further clarify which foreign facilities must register – that is, what are de minimis as opposed to "significant" activities – FDA should also give examples of types of processing or handling activities that it does not consider de minimis. Without such clarification, foreign facilities have too much discretion to determine whether they are subject to the registration requirements.

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[2] 68 Fed. Reg. 5377, 5380 (Feb. 3, 2003).

[3] 68 Fed. Reg. at 5380.

2. *FDA Should Require Specific Product-Category Information As Part of the Registration Requirement*

Section 305 of the Bioterrorism Act provides that the FDA may require registrants to submit the general food categories of food manufactured, processed, packed or held at the facility, if FDA determines through guidance that such information is necessary. FDA has stated its intention to issue guidance. In the preamble to the proposed rule, FDA stated its tentative conclusion that "information on the category of food manufactured, processed, packed, or held at each facility that must register is necessary for a quick, accurate, and focused response to a bioterrorist incident or other food-related emergency, because the categories will assist FDA in conducting investigations and surveillance operations in response to such incident."[4] The FDA views such information as a "key element" for both FDA and the food industry to allow for rapid communication to facilities directly impacted by an actual or potential bioterrorism attack or other food related emergency.[5] The FDA has also stated that food product categories will allow it to quickly alert facilities potentially affected by such an incident if it receives information indicating the type of food affected.[6] We agree that such information is crucial to FDA's effective implementation of this provision.

Despite the recognized importance of specific product category information, in the optional information section of the proposed rule, the FDA would allow facilities to simply check a box indicating that they produce or process "most/all food product categories" under 21

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[4] 68 Fed. Reg. at 5384.

[5] 68 Fed. Reg. at 5385.

[6] 68 Fed. Reg. at 5384.

C.F.R. § 170.3.[7] This optional category should be deleted, especially as it would bring such facilities under the jurisdiction of the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture.

Allowing facilities to provide less specific product category information by checking a "most/all" box is inconsistent with FDA's finding that product category information is necessary to provide a more focused response in the event of a bioterrorism event. If there is a food-related emergency, it could result in a delay since FDA would be unnecessarily contacting facilities that do not make, process, handle or hold the precise food in question. Moreover, a facility could manufacture or process different food products or delete other food products almost daily. Yet, it would not be required to notify FDA of any changes.

Requiring more specific product category information as part of the registration requirement is particularly important with respect to imported foods. In 1998, the General Accounting Office identified the safety of FDA-regulated imported foods as an area of particular concern, finding that "relying on port-of-entry inspections to detect and prevent unsafe foods is ineffective."[8] However, because the FDA still lacks statutory authority to inspect foreign facilities to assure that they have U.S.-equivalent food-safety programs in place before importing their products, the registration process affords one means to increase the effectiveness of port-of-entry inspections.

Indeed, in justifying the need for product category information, the FDA has stated that it

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[7] 68 Fed. Reg. at 5385. FDA regulations, 21 C.F.R. § 170.3(n), establish numerous general food categories to group specific related foods together for the purpose of establishing tolerances or limitations for the use of direct human food ingredients.

[8] U.S. General Accounting Office, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, GAO/RCED-98-103 (Apr. 1998), p. 3.

will aid in identifying any discrepancies between registration information and information provided in the notice required prior to shipment of imports. Since FDA inspectors rely, in part, on importers' descriptions of shipment contents when making decisions on which shipments to inspect, inspectors need the best data available to target imported foods that may pose a health or security threat. Therefore, requiring specific product-category information as part of registration may help to more closely focus inspection resources.

3. *FDA Should Require Mandatory Notification When A Facility Goes Out of Business*

Under section 1.234(a) of the proposed rule, facilities would be required to submit an updated registration within 30 calendar days of any change to information previously provided. In addition, the proposed rule stated that "[a] facility canceling its registration must do so on the cancellation of registration form."[9] As written, the language of the proposed rule is too weak and fails to impose any affirmative obligation on a facility that goes out of business to inform FDA or submit a notice of cancellation.[10]

The rule should be redrafted to require facilities that go out of business to submit a notice of cancellation of their registration as soon as possible but in no event later than 15 calendar days. Updated information on a facility's business status would help assure that if there is a bioterrorism event, the FDA is not wasting resources by attempting to contact facilities that no longer exist or are out of business. Requiring cancellation of registration would also help assure that an organization or group cannot threaten the American food supply by using a former business's registration as a means to import or distribute tainted products into or within the

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[9] Proposed rule §1.234(b); *see also* 68 Fed. Reg. at 5386.

[10] In the preamble to the proposed rule, FDA states that "facilities that go out of business would need to notify FDA of the cancellation of their registration." 68 Fed. Reg. at 5394. However, that requirement is not reflected in the actual language of the proposed regulation.

United States. Such a loophole would render the protections sought by Congress under the Bioterrorism Act meaningless.

4. *FDA Should Clarify The Provisions Warranting Revocation/Suspension of Registration*

The Bioterrrorism Act provides that a failure to register by either a domestic or foreign facility is considered a prohibited act under the Food Drug and Cosmetic Act.[11] If a covered facility fails to register, the FDA has specified remedies, including the ability to bring criminal and civil actions.

The FDA has requested comments on the circumstances under which a firm's registration should be considered null and void or revoked.[12] The rules should distinguish between registration violations that would warrant a suspension as opposed to a revocation or nullification of the registration.

For instance, for the reasons set forth above, a facility's failure to inform FDA within the requisite time period that it has gone out of business could have serious consequences. Therefore, such a failure should be grounds for automatic revocation of a registration. Likewise, circumstances that would warrant a revocation are those that undermine the stated purposes of the registration requirement, which is to provide FDA with information necessary to respond in a prompt manner to a bioterrorist or other event that threatens the security of the food supply. At a minimum, this would include submission of a registration containing false information.

In addition, FDA should consider a less drastic remedy of suspension where a facility fails to provide required updated information within applicable time periods. A facility that has

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[11] 21 U.S.C. § 331.

[12] 68 Fed. Reg. at 5386.

failed to meet its obligation to provide updated information or has provided incomplete registration information should be notified by FDA both electronically and by written letter that the agency has reason to believe that the registration information is inaccurate or incomplete. The registrant should be advised that a failure to provide the required information within 15 business days will result in a suspension of registration unless information or an explanation of why such information is unavailable is provided.

If the facility fails to respond or provide the requisite information within the specified time period, the registration should be suspended. Once the requisite information is provided, a facility's registration could be reinstated.

5. *FDA Lacks Authority to Create Additional Exemptions to the Registration Requirement*

In the preamble to the proposed rule, FDA recognized that the registration requirements may impose on covered facilities additional regulatory burdens, including the submission of duplicative information.[13] Accordingly, the agency has asked for comment on whether it has authority, under the Bioterrorism Act or other regulatory mandate, to grant a partial or full exemption from the FDA registration requirement to facilities that may have already registered with another Federal agency.

We believe that FDA does *not* have authority to create exemptions from the registration requirements not otherwise expressly created in the Bioterrorism Act. The question of whether FDA has authority to create additional exemptions to the Act's requirements is a matter of statutory construction. The Act mandates that the Secretary shall by regulation, require that any "facility" engaged in manufacturing, processing, packing, or holding food for consumption in the

[13] 68 Fed. Reg. at 5386.

United States be registered.[14] In defining what constitutes a "facility," Congress specifically provided that the term does not include farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared for or served directly to the consumer, or fishing vessels not engaged in processing.[15] The Act also defines "foreign facility" in a manner that does not include those facilities where food from such a facility undergoes further manufacturing/processing by another foreign facility outside the United States.[16] As a result, through the definition of "facility," Congress has explicitly identified which facilities are subject to and which are exempt from the registration requirement.

Congress may delegate policy making authority to an agency either through an express delegation or the introduction of an interpretative gap in the statutory structure.[17] Thus, for instance, if Congress had failed to define the term "facility," FDA would have interpretative authority to define the term. Here, however, Congress has "directly spoken to the precise question at issue."[18] The language of section 415(b) is specific and definite in identifying what is a facility under the Act and therefore subject to the registration requirement. This specificity means that Congress has not delegated to FDA authority to constrict the definition of "facility" as a means of exempting certain facilities from that requirement in order to reduce their regulatory

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[14] Public Health Security and Biopreparedness and Response Act of 2002, H.R. 3448, Section 415(a)(1) [hereinafter Bioterrorism Act]..

[15] Bioterrorism Act, Section 415(b)(1).

[16] Bioterrorism Act, Section 415(b)(3)(A).

[17] *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 696-97 (1991); *National Fuel Gas Supply Corp. v. FERC*, 811 F.2d 1563, 1569 (D.C. Cir.) (A delegation of authority can occur "either explicitly by authorizing the agency to adopt implementing regulations, or implicitly by enacting an ambiguously worded provision that the agency must interpret"), *cert. denied*, 484 U.S. 869 (1987).

[18] *Chevron U.S.A., Inc. v. Natural Resources Defense Council,* 467 U.S. 837 (1984).

burden and the agency would be exceeding its statutory authority to do so.[19]

Moreover, it is clear that Congress recognized the additional regulatory burden that the registration provisions may impose. In section 305(d), it specifically stated that "[f]or the purpose of reducing paper-work and reporting burdens," the agency could provide for and encourage the use of electronic methods for filing. Yet it did not authorize an exemption for facilities that may be registered with other federal agencies as a means of minimizing their burden.[20]

Apart from the fact that FDA lacks authority to create either a partial or full exemption for facilities that are already registered with other federal agencies, such action also would be inconsistent with the underlying purpose of the Act – which is to provide FDA with access to information necessary to respond quickly in the face of a public health threat to the food supply. Facilities who must register with other federal agencies may do so for entirely different purposes. Likewise, facilities may be required to provide different types of information than required by the registration provisions, they may not be subject to the same requirements for updating that information, or the information may be in a different format (paper as opposed to electronic).

Moreover, in the event of a true emergency where a prompt response would be crucial, FDA could lack immediate access to the information or face a delay in obtaining it. Each agency has its own rules and procedures for sharing information with other federal agencies. Even where the agencies are in agreement on readily sharing information, they may be unable to

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[19] See *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1060 (D.C. Cir. 1995) (refusing to "presume a delegation of power merely because Congress has not expressly withheld such power").

[20] "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Bates v. United States*, 522 U.S. 23, 29-30 (1997) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)).

do so because of technical incompatibilities. Therefore, as both a matter of law and policy, the FDA cannot and should not create exemptions from the registration requirements other than those explicitly authorized by statute.

6. *FDA Should Reject Other Options*

For the purpose of comparing the cost of the registration requirement as set forth in the proposed rule, FDA also identified several other options it considered. One of those options – identified as Option Five – is identical to the proposed rule in that it would require registration of domestic and foreign facilities that manufacture, process, pack or hold food that sell their products in both interstate and intrastate commerce for consumption in the United States. However, it would not require as much information from registrants. In particular, it would not require registrants to submit the general food product categories under section 170.3. According to FDA, removing the product categories from the registration "would decrease the frequency with which facilities have to update their registrations and reduce the amount of time required to register by 15 minutes."[21]

While this option would minimally reduce some of the costs associated with the proposed regulations, it would seriously undermine the goals and benefits of the proposed rule. FDA would lack crucial information necessary to identify facilities that manufacture, process, or store food products subject to an actual or perceived threat in a timely and efficient manner. It would affect the agency's ability to trace suspect food backward and forward through the distribution chain. It would greatly reduce FDA's ability to respond quickly to an attack on the food supply in order to prevent an illness outbreak and public health emergency.

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[21] 68 Fed. Reg. at 5401.

An underlying purpose of the Bioterrorism Act is to "establish an information system that would allow FDA to have a more integrated picture of the food distribution system."[22] As FDA has explained, the registration regulation "addresses an important aspect of this information system: The need to know what facilities manufacture/process, pack, or hold food for consumption in the United States, **what types of food each facility handles**, and how each facility can be contacted."[23] Not only would adoption of Option 5 be contrary to congressional intent in enacting the Bioterrorism Act, exempting facilities from providing food product category information would deprive FDA of one of its most important tools for effectively deterring and responding to any actual or potential terrorist attack on the American food supply.

Conclusion

As long as the American food supply remains vulnerable to terrorist attack, the agencies responsible for protecting the food supply must have the best tools available to identify and respond to any actual or perceived threat. While the registration provisions of the proposed rule represent an important part of FDA's effort to create an integrated picture of the food distribution system, the proposed rule should be strengthened to further assure that the agency has the most crucial information and data necessary to identify foods that may pose a health or security threat.

Respectfully submitted,

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[22] 68 Fed. Reg. at 5388.

[23] 68 Fed. Reg. at 5388 (emphasis added).

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